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23448 7590 06/23/2010

INTELLECTUAL PROPERTY / TECHNOLOGY LAW PO BOX 14329

RESEARCH TRIANGLE PARK, NC 27709

EXAMINER
MOORE, WILLIAM W

ART UNIT PAPER NUMBER

1656 DATE MAILED: 06/23/2010

 APPLICATION NO.
 FILING DATE
 FIRST NAMED INVENTOR
 ATTORNEY DOCKET NO.
 CONFRMATION NO.

 10/567.073
 03/07/2006
 Phillip N. Bryan
 4115-181
 2283

TITLE OF INVENTION: ENGINEERED PROTEASES FOR AFFINITY PURIFICATION AND PROCESSING OF FUSION PROTEINS

 APPLN, TYPE
 SMALL ENTITY
 ISSUE FEE DUE
 PUBLICATION FEE DUE
 PREV, PAID ISSUE FEE
 TOTAL FEE(S) DUE
 DATE DUE

 nonprovisional
 NO
 \$1510
 \$300
 \$0
 \$1810
 09/23/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

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IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

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							(Date)	
APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR		ATTORNEY DOCKET NO. CONFIRMA		CONFIRMATION NO.	
10/567,073 TITLE OF INVENTION	03/07/2006 I: ENGINEERED PROT	EASES FOR AFFINITY	Philip N. Bryan PURIFICATION AND PF	COCESSING OF FU	SION	4115-181 PROTEINS	2283	
APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE	FEE	TOTAL FEE(S) DUE	DATE DUE	
nonprovisional	NO	\$1510	\$300	\$0		\$1810	09/23/2010	
EXAM	IINER	ART UNIT	CLASS-SUBCLASS]				
MOORE, W		1656	435-069700	•				
"Fee Address" ind PTO/SB/47; Rev 03-0 Number is required. 3. ASSIGNEE NAME A	ondence address (or Cha B/122) attached. ication (or "Fee Address)2 or more recent) attach ND RESIDENCE DATA	nge of Correspondence "Indication form ed. Use of a Customer A TO BE PRINTED ON	(I) the names of up to or agents OR, alternati (2) the name of a singl registered attorney or a 2 registered patent atto- listed, no name will be ITHE PATENT (print or typ	For printing on the patent front page, list the names of up to 1 registered patent attorneys agents OR, alternatively, the name of a single firm thaving as a member a gistered attorney or agent and the names of up to registered patent antervays or agent. If no name is died, no name will be printed. The name will be printed.				
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	s SMALL ENTITY state	is. See 37 CFR I.27.	☐ b. Applicant is no lon					
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PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.



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10/567,073	03/07/2006	Philip N. Bryan	4115-181	2283		
23448	7590 06/23/2010		EXAMINER			
INTELLECTU	AL PROPERTY / TEC	MOORE, WILLIAM W				
PO BOX 14329		ART UNIT	PAPER NUMBER			
RESEARCH TRI	ANGLE PARK, NC 27	1656				

DATE MAILED: 06/23/2010

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 138 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 138 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Application No. Applicant(s) 10/567.073 BRYAN, PHILIP N. Notice of Allowability Examiner Art Unit WILLIAM W MOORE 1656 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. 1. X This communication is responsive to the amendment filed 3 June 2010 and the interview conducted 21 June 2010. The allowed claim(s) is/are 1, 4, 6, 7, 9-11, 13, 15-17 and 63-65. 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) \square All b) ☐ Some* c) ☐ None of the: 1. T Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). * Certified copies not received: _____. Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). 6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL. Attachment(s) 1. | Notice of References Cited (PTO-892) 5. Notice of Informal Patent Application 2. Notice of Draftperson's Patent Drawing Review (PTO-948) Interview Summary (PTO-413), Paper No./Mail Date Information Disclosure Statements (PTO/SB/08). 7. X Examiner's Amendment/Comment Paper No./Mail Date 4. T Examiner's Comment Regarding Requirement for Deposit 8. X Examiner's Statement of Reasons for Allowance of Biological Material 9. ☐ Other .

/William W. Moore/ Examiner, Art Unit 1656 Application/Control Number: 10/567,073 Page 2

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EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. All allowed claims, whether or not amended, are presented below to assist the printer.

Delete claims 3, 12, and 46-49.

Amend claims 1, 6, 7, 9-11, and 15-17 thus:

- 1. (Currently amended) A nucleic acid construct encoding a fusion protein, wherein the construct comprises a coding sequence for a protein of interest and a coding sequence for a subtilisin prodomain protein, wherein the fusion protein comprises the protein of interest operatively linked to the C-terminus of the subtilisin prodomain protein, wherein the subtilisin prodomain protein is modified to bind binde to a subtilisin or a variant thereof with a Kd of 10 nM or less and to form a stable complex, wherein the subtilisin or variant thereof is effective to cleave the protein of interest from the subtilisin prodomain protein, and wherein the subtilisin prodomain protein remains bound to the subtilisin or variant thereof following cleavage of the protein of interest from the modified subtilisin prodomain.
- 4. (Previously Presented) The nucleic acid construct according to claim 1, wherein the subtilisin prodomain protein comprises a variant of SEQ ID NO:2, wherein the variant comprises a substitution at one or more of positions P4 P4 that correspond to the positions P4 through 77 of SEQ ID NO:2 wherein the substitution comprises any of F or Y substituted for the amino acid at the position corresponding to position 74 of SEQ ID NO:2 P4, any amino acid residue substituted for the amino acid at the position corresponding to position 75 of SEQ ID NO:2 P3, A or S substituted for the amino acid at the position corresponding to position 76 of SEQ ID NO:2 P3, and M, F, Y H, or L substituted for the amino acid at the position corresponding to position 75 of SEQ ID NO:2 P4.
- 6. (Currently amended) The nucleic acid construct according to claim 1, wherein the <u>C</u>terminus of the subtilisin prodomain protein comprises substitutions of amino acid residues F or Y for the amino acid at the position corresponding to position 74 of SEQ ID NO:2 P4, any amino acid residue for the amino acid at the position corresponding to position 75 of SEQ ID NO:2 P3. A or S for the amino acid at the position corresponding to position 76 of

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SEQ ID NO:2 P24, and M, F, Y, H, or L for the amino acid at the position corresponding to position 77 of SEQ ID NO:2 P4 at the C-terminal end.

- 7. (Currently amended) A fusion protein comprising a terget protein of interest operatively linked to the C-terminus of a subtilisin prodomain protein, wherein the subtilisin prodomain protein is modified to bind to a subtilisin or a variant thereof with a Kd of 10 nM or less and to form a stable complex exhibit an increased affinity for subtilisin or a variant thereof, as empered to an unmodified subtilisin prodomain protein, and wherein the subtilisin or variant thereof is effective to cleave the terget protein of interest from the subtilisin prodomain protein, and wherein the subtilisin prodomain protein remains bound to the subtilisin or variant thereof following cleavage of the terget protein of interest from the modified subtilisin prodomain.
- (Currently amended) The fusion protein according to claim 7, wherein the subtilisin
 prodomain protein comprises the substitution of amino acids at positions that correspond to
 the positions 74 through 77 of SEQ ID NO:2 P4-P4 with the amino acid sequence set forth in
 SEQ ID NO:10 FKAM (SEQ ID NO: 10).
- (Currently amended) The fusion protein according to claim 7, wherein the subtilisin
 prodomain protein comprises the amino acid sequence set forth in SEQ ID NO:7 EED K-L
 (E/Y) Q-S (M/L/Y) (SEQ ID NO: 7).
- 11. (Currently amended) The fusion protein according to claim 7, wherein the target protein of interest is staphylococcal Protein AB domain; Protein AB mutant A219; Streptococcal protein GB domain; Streptococcal protein GB domain; Streptococcal protein GB mutant G311; E. coli hypothetical Yab; Bovine a-subunit of transducin; M. thermautotrophicus CDC6; streptavidin; avidin; Taq polymerase; an alkaline phosphatase; a Rhase; a DNase; a restriction enzyme enzymes; a peroxidase peroxidases; an endo-1,4- beta glucanase; an endo-1,3-beta-glucanase; a chitinase ehitinases; a beta glucosidase; and an alpha glucosidase glucosidase; and an alpha glucosidase glucosidase; a beta glucoronidase; and an alpha glucoronidase glucoronidases; a lotrampterase glucosyl-transferases; a phosphotransferase; an esterase esterases; a lotramphenicol-acetyl-transferase; a beta-lactamase; a luciferase; an esterase esterases; a lipase lipases; a protease proteases; a bacteriocine bacteriocines; an antibiotici entibiotics; an enzyme inhibitor inhibitors; a growth factor feeters; a hormone hormones: a receptor receptors: a membrane protein ereteins: a nuclear

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<u>protein proteine</u>; <u>a</u> transcriptional <u>factor</u>; <u>a</u> translational <u>factor</u>; <u>factore</u> or <u>a</u> nucleic acid modifying enzyme <u>enzymee</u>.

13. (Currently amended) A method for the production of a subtilisin binding fusion protein, the method comprising:

providing a nucleic acid construct encoding a fusion protein wherein the fusion protein comprises a protein of interest operatively linked to the C-terminus of a subtilisin prodomain protein wherein the subtilisin prodomain protein is modified to bind subtilisin or a variant thereof with a Kd of 10 nM or less and to form a stable complex increased affinity as compared to an unmedified subtilisin prodomain protein, wherein the subtilisin or variant thereof is effective to cleave the protein of interest from the prodomain protein, and wherein the subtilisin prodomain protein remains bound to the subtilisin or variant thereof following cleavage of the protein of interest of interest from the modified subtilisin prodomain;

transfecting a host cell with the nucleic acid construct; and

culturing the transformed host cell under conditions suitable for expression of the fusion protein.

- (Currently amended) The method according to claim 13, wherein the subtilisin prodomain is
 modified by replacing the P4 through PI amino acids at positions that correspond to the
 positions 74 through 77 of SEQ ID NO:2 with an amino acid sequence set forth in SEQ ID
 NO:10. SEQ ID NO:11. or SEQ ID NO:12 FKAM (SEQ ID NO: 10), FKAY (SEQ ID NO:
 11) or FKAF (SEQ ID NO: 12).
- 16. (Currently amended) The method according to claim 15, wherein the protein of interest is staphylococcal Protein AB domain; Protein AB mutant A219; Streptococcal protein GB domain; Streptococcal protein Ga domain; Protein GB mutant G311; E. coli hypothetical Yab; Bovine a-subunit of transducin; M. thermautotrophicus CDC6; streptavidin; avidin; Taq polymerase; an alkaline phosphatase; a RNase; a DNase; a restriction enzyme enzymee; a peroxidase peroxidases; an endo-1,3-beta-glucanase; a chitinase ehitinases; a beta glucosidase; end an alpha glucosidase; end an alpha glucosidase; end an alpha glucosidase; and anylase; a glucosyltransferase elucesyltransferase; a phospho-transferase; a phospho-transferase; a chloramphenicol-acetyl-transferase; a beta-lactamase; a luciferase; an esterase exterasees; a lipase lipases; a protease proteaseses; a bacteriocine besteriocines; an antibiotic entibiloties; an enzyme inhibitor inhibitors; a growth factor factors; a hormone hermones; a receptor receptors; a membrane protein preteins; a nuclear protein preteins; a

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transcriptional <u>factor</u> feeters; <u>a</u> translational <u>factor</u>; factors or <u>a</u> nucleic acid modifying enzyme enzymes.

 (Currently amended) The method according to claim 13, wherein the host cells includes cells from Escherichia coli, Bacillus, Salmonella, Pseudomonas, [[;]] Saccharomyces cerevisiae, Pichia pastoris, Kluveromyces, Candida, Schizosaccharomyces; or CHO cells.

Add the new claims 63-65:

- 63. (New) A nucleic acid construct encoding a fusion protein, wherein the construct comprises a coding sequence for a protein of interest and a coding sequence for the amino acid sequence set forth in SEQ ID NO:7 wherein the fusion protein comprises the protein of interest linked to the C-terminus of the amino acid sequence set forth in SEQ ID NO:7.
- 64. (New) A fusion protein comprising a protein of interest linked to the C-terminus of the amino acid sequence set forth in SEQ ID NO:7.
- 65. (New) A method for the production of a fusion protein, the method comprising: providing a nucleic acid construct encoding a fusion protein wherein the fusion protein comprises a protein of interest linked to the C-terminus of the amino acid sequence set forth in SEQ ID NO:7;
 - transfecting a host cell with the nucleic acid construct; and
 - culturing the transformed host cell under conditions suitable for expression of the fusion protein.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Kelly K. Reynolds on 21 June 2010.

The following is an examiner's statement of reasons for allowance:

Applicant's amendments to claims 1, 7, and 13 filed 3 June 2010 state those features of the invention disclosed, e.g., in Example 6 at pages 25 and 26 of the specification, that distinguish it over the prior art of record herein, and examiner's amendments of claim 1-10 and 15 above to uniformly state the features of modified subtilisin prodomains enabled and adequately described by the disclosure of the specification, wherein two distinct regions of such prodomains may be modified to provide the required binding constant and the capacity to form a stable complex with a subtilisin that can persist after release of a desired fusion partner, and to clarify the recitations with reference to the structure of a typical prodomain set forth in SEQ ID NO:2. Claims 6, 9-11, 16, and 17 are also amended above to correct informalities and to clarify their subject matters.

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New claims 63-65 are added so that the allowed claims include the subject matter disclosed at page 25, lines 4-9, of the specification, thus claims 1, 4, 6, 7, 9-11, 13, 15-17 and 63-65 are allowed herewith.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Manjunath Rao, can be reached at 571.272.0939. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

/William W. Moore/ Examiner, Art Unit 1656

/Nashaat T Nashed/

Primary Examiner, Art Unit